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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,382	03/07/2001	Reynolds Paul Ross	681353342002	2369

7590

11/25/2002

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EXAMINER

HENDRICKS, KEITH D

ART UNIT

PAPER NUMBER

1761

DATE MAILED: 11/25/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,382

Applicant(s)

ROSS ET AL.

Examiner

Keith Hendricks

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 and 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

NOTE: The following rejections are maintained from the previous Office action, as the claims have not been amended to overcome the issues, and/or applicant did not traverse the rejections.

In claim 1:

- Part (c), it is unclear what steps are to be performed if the pH already falls within the recited range of 6.3 to 6.7, thus lacking the need to be "adjusted".

As amended, the claim currently reads: "adjusting the pH of the fermentation within the range from about 6.3 to 6.7". This implies that the pH is already "within" this range, and does not define the term "adjusted", as to how and to what points within the range it is to be adjusted. It is believed, however, that the intent of applicants is to claim the "adjustment" of the pH of the medium *to* within the recited range, as was suggested in the previous Office action. However, also as stated therein and above, it is unclear what steps are to be performed if the pH already falls within the recited range of 6.3 to 6.7, thus lacking the need to be "adjusted".

- In part (d), it is unclear as to how the step of "inactivating the bacterial fermentate" is to be carried out. Further, it is unclear as to what portion(s) and activity, or activities, the fermentate itself possesses, which would need to be inactivated. Note that this phrase is not necessarily equivalent to "inactivating the bacteria within the fermentate". The claims may be amended as such, if this is the intended meaning, and if this is supported by the specification.

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In claim 2:

- It is unclear as to how the powders recited may be used as the medium to be inoculated with the bacteria, whereby a presumably liquid fermentate is evaporated from the culture medium (as in claim 1, step (e)). It is believed that these should be reconstituted powders, but this is unclear from the claims. Support from the specification is required if amended as such. ✓

Claim 13 is indefinite, as it fails to further define over the product of claim 11 or 12, as no further components are recited that would serve to distinguish the "food product comprising a spray-dried lacticin 3147" in claim 13, over the "spray-dried lacticin 3147" of claims 11-12. ✓

Claim 14 is indefinite, as the terms "dessert" and "custard" are not mutually exclusive options as claim limitations. A "custard" is a "dessert", and thus the metes and bounds of the claimed invention are unclear. ✓

The term "increased" in claim 15 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. ✓

Claim 15 improperly depends from two different claims, requiring the limitations of both at the same time (by the term "and"). Reference to multiple claims should be in the alternative. }

Again, in *both* the claims and specification, terms such as "pasteurisation", "crystallised", etc. should be spelled in accordance with accepted U.S. language, as this is a U.S. filed application. It is noted that (a) the specification was not amended as such, and (b) claim 2, line 3 contains the term "pasteurised."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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i) Claims 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by McAuliffe et al., of record, published February 1999 (vol. 2). The reference and rejection are incorporated as cited in a previous Office action.

Applicants' arguments filed September 13, 2002, have been fully considered but they are not persuasive. At page 5 of the response, applicants state that the product of McAuliffe et al. is produced by bacteria grown in a "complex nutrient medium" which is not suitable as a food ingredient, and therefore is not a commercial food additive. This is not deemed persuasive, as a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). It is noted, however, that only claims 11-13 have been rejected. These claims do not recite a "food ingredient", nor any other intended use. As stated in the rejection under 35 U.S.C. 112, second paragraph above, claim 13 fails to further define over the product of claim 11 or 12, as no further components are recited that would serve to distinguish the "food product comprising a spray-dried lacticin 3147" in claim 13, over the "spray-dried lacticin 3147" of claims 11-12.

Applicants state that "the product claimed is not lacticin 3147, [but rather] it is a concentrate capable as a formulation as a spray-dried powder." This is not deemed persuasive, as claim 12 is specifically drawn to a "spray-dried lacticin 3147." No other components are present. It is not claimed as a "concentrate", or as part of a "spray-dried powder *containing* lacticin 3147." As previously stated on the record, lacticin 3147 in any form, spray-dried or otherwise, is still the same compound. The preparation of a known product in a specific physical form does not render novel said known product.

ii) Claims 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ryan et al. (WO 96/32482). The reference and rejection are incorporated as cited in a previous Office action.

Applicants' arguments filed September 13, 2002, have been fully considered but they are not persuasive. At page 5 of the response, applicants state that Ryan discloses a freeze-dried powder, whereas the instant claims describe the production of a "concentrate made by a different process and therefore having different physical properties, e.g. it that [sic] may be formulated as a spray-dried powder." This is not deemed persuasive for the reasons of record. Applicants have provided no support for the statement that the dried powder of Ryan et al. is physically different from the dried powder of the

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instant claims. As stated above, a structural difference must exist between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, and/or possesses the same physical properties, then it meets the claim. In a claim drawn to a product-by-process, the process must result in a manipulative difference in the product, as compared to the prior art. As previously stated on the record, lacticin 3147 in any form, spray-dried or otherwise, is still the same compound. The preparation of a known product in a specific physical form does not render novel said known product.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan et al. (WO 96/32482), in view of DE 2616390 (English abstract provided). The references and rejection are taken as cited previously of record.

Applicants' arguments filed September 13, 2002, have been fully considered but they are not persuasive. At page 7 of the response, applicants raise several potential scenarios in an attempt to show that the claimed invention would not have been obvious to one of ordinary skill in the art. These are not deemed persuasive.

Applicants state that "many bacteriocins are heat labile", and that there is even "a class of bacteriocins which are called heat-labile bacteriocins." This, however, does not speak to the specific lacticin compound as claimed, namely lacticin 3147. Applicants do state that "it couldn't be predicted that lacticin 3147 could withstand these temperatures and survive the heat treatment steps involved in spray-drying." Initially, it is noted that not all claims are directed to a spray-drying process step, or a spray-dried product. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., spray-drying) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26

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USPQ2d 1057 (Fed. Cir. 1993). In fact, several of the claims are directed to the simple “evaporation” of the fermentate, at low temperatures.

Applicants’ ‘potential failure’ scenarios are unsupported, and at best, are speculation. The prior art references demonstrate a reasonable expectation of success, both from the knowledge in the art concerning the lacticin 3147 compound itself, and the general state of the art of spray-drying other bacteriocin compounds. It is noted that both lacticin 3147 and nisin (DE 2616390) are derived from strains of the *same species and subspecies* of bacteria, namely *Lactococcus lactis*, subsp. *lactis*. Therefore, the thermostability of one compound must be at least equal to that of the other, in order for the microorganism to survive at a particular temperature, and for the compounds to be active at such temperatures. Regarding the concept of dehydration of the lacticin protein, it is noted that *Lactococcus lactis*, subsp. *lactis* microbes are shipped from the ATCC depository freeze-dried, and thus it would not be expected that a dehydration of the *medium* in which the lacticin protein is present, would yield additional difficulty. It is important to note that applicants’ arguments are conflicting, as the statements at page 7 appear to imply the direct dehydration of the lacticin alone, which is not claimed, yet applicants had also stated at page 5, “the product claimed is not lacticin 3147”, but rather a concentrated culture media containing the protein.

Finally, it is noted that one of ordinary skill in the art would indeed have known much about the thermostability of lacticin 3147. This was a well-characterized protein, known in the art for decades. To support this position, reference is made to page 439, col. 1, of McAuliffe et al., 1998 (submitted in the most recent IDS), which states that “lacticin 3147 is a bacteriocin produced by *Lactococcus lactis*, subsp. *lactis* DPC3147... [and] is a heat-stable compound.” This reference is not required as part of the obviousness rejection, but rather is noted in rebuttal of applicants’ arguments.

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Conclusion


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (703) 308-3959. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3602 for regular communications and (703) 872-9565 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


KEITH HENDRICKS
PRIMARY EXAMINER